

REMARKS

Claims 21-41 were pending in the application. Claims 21 and 24-27 have been amended. The amendments are supported fully by the claims and/or specification as originally filed and, thus, do not represent new subject matter. Upon entry of these amendments, Claims 21-41 will be pending and under active consideration. Claims 21, 32, 34, and 41 are independent.

Claim 21 has been amended to recite a "functional food or functional feed composition comprising a resistant starch obtained from a water-insoluble linear α -1,4-D-glucan." The terms "functional food" and "functional feed" have been added and the alternative composition comprising a "water-insoluble linear α -1,4-D-glucan" has been removed to leave a "resistant starch obtained from a water-insoluble linear α -1,4-D-glucan." The amendment is supported fully by the claims and/or specification as originally filed and, thus, does not represent new subject matter. In particular, support for "functional food or functional feed" is found at page 1, lines 16-20, and page 3, lines 1-7, of the specification as filed. Claims 24-26 are amended to conform to Claim 21, as amended.

Claims 27-29 have been amended to remove the superfluous term "MW" following "molecular weight."

Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

I. **The Rejection Over Kossman *et al.* (WO 95/31553) Under 35 U.S.C. § 102(b) Should Be Withdrawn**

Claims 21, 22, 24-26, 30-37 and 39-41 are rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Kossman *et al.* (WO 95/31553)(hereinafter, "Kossman") for the reasons of record. In particular, the Office Action alleges that Kossman describes a linear, unbranched α -1,4 glucan, its production from sucrose using amylosucrase, its usefulness in all of the applications to which amylose can be put, the "enrobed" embodiment as recited in claim 26, and the method recited in claim 41 (alleged to be disclosed inherently by Kossman's disclosure of orally acceptable compositions containing the linear α -1,4 glucans, since a person orally consuming the glucans would inherently benefit from the preventive effect of the glucan). Applicants traverse respectfully.

Applicants submit respectfully that Kossman does not anticipate the rejected claims, as amended, because Kossman does not disclose each and every element of the claimed subject matter as required for a *prima facie* showing of anticipation. In particular, the claimed subject matter is directed to **resistant** starch obtained from a water-insoluble linear α -1,4-D-glucan. Without acquiescing in the allegation that Kossman teaches a linear α -1,4-D-glucan as claimed by Applicants, Applicants submit respectfully that Kossman does not teach or suggest the production or use of **resistant** starches. Kossman teaches only the production and use of linear α -1,4 glucans which, as described in Applicants' specification at page 4, lines 15-16, are **not resistant** to amylase digestion.

Likewise, Applicants submit respectfully that the method of Claim 41 is not anticipated by Kossman. Non-resistant starches (*i.e.*, linear α -1,4 glucans as described by Kossman) cannot be expected to reach the large intestine intact; therefore, non-resistant starches cannot provide the functional benefits to the intestinal flora provided by Applicants' claimed compositions. Accordingly, one who consumes the compositions taught by Kossman would ***not*** inherently benefit from the preventive effect of the glucan provided by Applicants' claimed compositions and method, as alleged in the Office Action.

In view of the above, Applicants submit respectfully that Claims 21, 22, 24-26, 30-37 and 39-41 are not anticipated by the Reference. Accordingly, Applicants request respectfully that the rejection of Claims 21, 22, 24-26, 30-37 and 39-41 under 35 U.S.C. § 102(b) be withdrawn.

II. The Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn

A. The Rejection Over Kossman *et al.* (WO 95/31553)

The Office Action, at pages 5-6, rejects Claims 21 and 27-29 under 35 U.S.C. § 103(a) as being allegedly obvious over Kossman *et al.* The Office Action alleges that Kossman describes the production of a linear α -1, 4 glucan from sucrose, using amylosucrase, and the use of the glucan in foods and pharmaceuticals. While admitting that Kossman differs from the claims in that Kossman does not disclose the molecular weight of the glucans, the Office Action alleges that the artisan of ordinary skill clearly would have recognized that molecular weight would be a function of the

duration of the synthetic reaction catalyzed by amylosucrase and would have been able to readily determine molecular weights of the glucan suitable for the various applications disclosed in Kossman. Applicants traverse respectfully.

As explained above, Kossman does not teach or suggest the use of resistant starches as claimed by Applicants. This deficiency is not cured by reference to further art, well known scientific principles, or otherwise. Therefore, without acquiescing in the allegation that one skilled in the art would have been able to readily determine molecular weights of the glucan suitable for the various applications disclosed in Kossman, Applicants submit respectfully that the burden of presenting a *prima facie* showing of obviousness under 35 U.S.C. § 103(a) has not been met.

Accordingly, Applicants submit respectfully that the rejection of Claims 21, and 27-29 under 35 U.S.C. § 103(a) has been overcome, and Applicants request respectfully that the rejection of Claims 21, and 27-29 under 35 U.S.C. § 103(a) be withdrawn.

B. The Rejection Over Kossman In View of Brown

The Office Action, at pages 6-7, rejects Claims 21-23 and 34-38 as being allegedly unpatentable over Kossman in view of Brown *et al.* (WO 96/082610)(hereinafter, "Brown") under 35 U.S.C. 103(a) for the reasons of record. In sum, the Office Action alleges that Kossman describes the production of a linear α -1, 4 glucan from sucrose, using amylosucrase, and the use of glucan in foods and

pharmaceuticals. While admitting that Kossman differs from the claims in that Kossman does not disclose the use of the glucan as a carrier when the beneficial agent is bifidobacteria, the Office Action alleges that Brown cures this deficiency by disclosing a pharmaceutical composition beneficial to the gastrointestinal tract, said composition comprising high amylose starch and bifidobacteria. Further, the Office Action alleges that Brown also discloses that starches containing over 80% amylose (i.e., over 80% linear α -1,4 glucan) are preferred. Accordingly, the Office Action concludes that the artisan of ordinary skill, recognizing from Kossman that unbranched linear α -1,4 glucans are suitable for use as carriers for beneficial agents, would allegedly have been motivated to have used Kossman's glucans as carriers for Brown's bifidobacteria. Applicants traverse respectfully.

As explained above, Kossman does not teach or suggest the use of resistant starches as claimed by Applicants. This deficiency is not alleged to be cured by Brown. Therefore, without acquiescing in the allegation that Brown cures the deficiency in Kossman relating to the use of the glucan as a carrier when the beneficial agent is bifidobacteria, or that Brown discloses a pharmaceutical composition beneficial to the gastrointestinal tract, said composition comprising high amylose starch and bifidobacteria as claimed by Applicants, Applicants submit respectfully that the burden of presenting a *prima facie* showing of obviousness under 35 U.S.C. § 103(a) has not been met.

In view of the above, Applicants request respectfully that the 35 U.S.C. § 103(a) rejection of Claims 21-23 and 34-38 be withdrawn.

III. The Rejections Under 35 U.S.C. § 112, Second Paragraph

At pages 2-3 of the Office Action, Claims 22 and 25 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out particularly and claim distinctly the subject matter regarded as the invention. The Office Action alleges that, in Claim 22, the recitation “prebiotics” is unclear. Further, the Office Action alleges that, in Claim 25, the recitation “microparticles” is unclear. Applicants traverse respectfully.

Respectfully, Applicants direct Examiner’s attention to page 9, lines 15-21, of the specification as filed which provide Applicants’ definition of the term “prebiotics.” Further, Applicants direct Examiner’s attention to page 10, lines 21-36, of the specification as filed which provide Applicants’ definition of the term “microparticles.” Applicants respectfully submit that the meanings of the rejected terms are clear and unambiguous in light of the teachings found in the specification as filed. Accordingly, Applicants request respectfully that the rejection of Claims 22 and 25 under 35 U.S.C. § 112, second paragraph, be withdrawn.

CONCLUSION

Applicants submit respectfully that the present application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

AUTHORIZATION

Applicants believe there is no fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,



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